IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ARBUTUS BIOPHARMA CORPORATION and GENEVANT SCIENCES GmbH, Plaintiffs, v. MODERNA, INC. and MODERNATX, INC., Defendants.	C.A. No. 22-252-JDW REDACTED - PUBLIC VERSION
MODERNA, INC. and MODERNATX, INC., Counterclaim-Plaintiffs, v. ARBUTUS BIOPHARMA CORPORATION and GENEVANT SCIENCES GmbH, Counterclaim-Defendants.	

MODERNA'S REPLY BRIEF IN SUPPORT OF ITS MOTIONS FOR SUMMARY JUDGMENT

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[1] Unless otherwise indicated, all emphasis has been added, and internal quotation marks, brackets, and citations have been omitted from quoted material.

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TABLE OF ABBREVIATIONS[2]

Abbreviation	Full Description
'069 patent	U.S. Patent No. 8,058,069 (Ex. 2)
'359 patent	U.S. Patent No. 8,492,359 (Ex. 5)
'378 patent	U.S. Patent No. 11,141,378 (Ex. 7)
'435 patent	U.S. Patent No. 9,364,435 (Ex. 6)
'651 patent	U.S. Patent No. 9,504,651 (Ex. 4)
'668 patent	U.S. Patent No. 8,822,668 (Ex. 3)
'069 Appeal	*Moderna TX, Inc. v. Arbutus Biopharma Corp.*, No. 2020-2329 (Fed. Cir.)
'069 IPR	*Moderna Therapeutics, Inc. v. Arbutus Biopharma Corp.*, IPR2019-00554 (P.T.A.B.)
'435 Appeal	*Moderna TX, Inc. v. Protiva Biotherapeutics, Inc.*, No. 2020-1184, -1186 (Fed. Cir.).
'435 IPR	*Moderna Therapeutics, Inc. v. Protiva Biotherapeutics, Inc.*, IPR2018-00739 (P.T.A.B.)
Arbutus	Arbutus Biopharma Corp.
Blenke	Blenke *et al.*, *Critical evaluation of quantification methods for oligonucleotides formulated in lipid nanoparticles*, 548 International J. Pharms. 793–802 (2018) (Ex. 60)
C-017	Contract No. W58P0522C0017 (Ex. 114), executed July 28, 2022
C-100	Contract No. W911QY20C0100 (Ex. 1), executed August 11, 2020
C-34	Contract No. 75A50120C00034 (Ex. 9), executed April 16, 2020
DOE	doctrine of equivalents
FAR	Federal Acquisition Regulation
Genevant	Genevant Sciences Gmbh
LNP	lipid nanoparticle
MacLachlan	U.S. Patent App. Pub. No. 2006/0008910 (Ex. 57)
Moderna	Collectively, Moderna, Inc. and Modernatx, Inc.

[2] Exs. 1 to 81 were filed with McLennan Declaration to Moderna's Opening Brief (D.I. 512-514); Exs. 82 to 119 with the McLennan Declaration to this Reply Brief.

Abbreviation	Full Description
mol % range limitations	Collectively, the cationic, non-cationic, conjugated lipid claim limitations recited in the Ratio Patents
ODP	Obviousness-Type Double Patenting
Op.	Opening Brief in Support of Summary Judgment
PHE	Prosecution history estoppel
Plaintiffs	Collectively, Arbutus and Genevant
POSA	Person of Ordinary Skill in the Art
PSOF	Plaintiffs' Affirmative Statement of Undisputed Facts, including Moderna's Responses
PTAB	Patent Trial and Appeal Board
PTO	U.S. Patent and Trademark Office
Ratio Patents	Collectively, the '069, '359, '668, '435 and '378 patents, of which only the '359, '435 and '378 patents remain asserted.
Resp.	Plaintiffs' Responsive Brief in Opposition to Summary Judgment
SOF	Moderna's Statements of Undisputed Facts, including Plaintiffs' Responses and Moderna's Reply
USG	U.S. Government

I. INTRODUCTION

Plaintiffs' opposition confirms that no material facts remain in dispute: (1) every one of the 500-million doses accepted under the C-100 Contract was "manufactured…for" USG with its express authorization and consent, triggering § 1498(a); (2) the intrinsic record shows Plaintiffs narrowed their lipid range claims to overcome the prior art disclosing the alleged equivalents, foreclosing DOE based on prosecution-history estoppel; and (3) the asserted claims reciting lipid "mol%" and "fully encapsulated" mRNA hinge on undefined, unmeasurable boundaries that leave a POSA unable to determine claim scope with reasonable certainty, rendering them indefinite. Summary judgment should therefore be entered for Moderna on all three grounds, and Plaintiffs' cross motions should be denied.

II. ARGUMENT

A. Claims Based on C-100 Contract Sales Are Barred Under § 1498(a)

1. Plaintiffs' Statutory Interpretation Ignores the Language of § 1498

Plaintiffs' opposition confirms that the material facts are undisputed: (1) Moderna manufactured 500,001,540 vaccine doses for USG pursuant to the C-100 Contract (SOF¶¶14, 20–21, 32), all of which USG accepted (SOF¶32); and (2) USG provided express authorization and consent through the C-100 Contract and its later Statement of Interest (SOF¶¶22–24; D.I. 49). That is all that is required for this Court to hold that § 1498 applies here. *See Sevenson*, 477 F.3d at 1365 (§ 1498 applies "if two criteria are met: (1) the use is 'for the Government'; and (2) the use is 'with the authorization and consent of the Government'"). As the Federal Circuit has explained, in such cases, courts need not go any further or look to other evidence because any manufacture or use under the contract occurs in the supplier's "capacity as a government contractor and pursuant to its contract ***for the benefit of the government***." *Id.* at 1366 (patentee's "specific factual arguments on the 'for the Government' question also fail" and are "irrelevant"). Summary

judgement should be granted in Moderna's favor.

Contrary to Plaintiffs' assertions, the correct inquiry under § 1498 is whether USG procured the goods in question with the requisite authorization and consent, which "is appropriately viewed as reflecting [USG's] determination that the contract is ***for [USG's] benefit***." D.I. 49 at 9; Op. 9 (citing 48 C.F.R. § 27.201-1), 11. Indeed, Congress instructs that executive agencies "shall" use procurement contracts like the C-100 "when the principal purpose of the instrument is to acquire … property or services ***for the direct benefit*** or ***use*** of [USG]." 31 U.S.C. § 6303(1). Given this statutory framework, in a direct procurement contract with FAR 52.227-1 clauses—like the C-100 Contract—there is ***no*** ambiguity that the contracted-for goods were "manufactured … for" USG pursuant to § 1498. Put another way, when USG has authorized and consented to the manufacture of goods in a government procurement contract, then the statutory standard is met (because the statute tells USG to use a procurement contract when the manufacture is for the direct benefit of USG). Accordingly, the contract then answers both prongs—the vaccines were manufactured ***for USG*** (pursuant to a procurement contract), and USG obviously authorized their manufacture as the allegedly infringing good ***is the good that was contracted for***.

Plaintiffs' accusation that Moderna uses *Sevenson* to collapse the § 1498 inquiry into a single authorization-and-consent prong (Resp. 3) is merely a strawman to disguise ***Plaintiffs'*** attempt to impose requirements not found in the statutory text. As a glaring example, Plaintiffs erroneously argue that § 1498 cannot apply for doses that were not ultimately administered to USG's own personnel. That myopic conception of § 1498 is legally incorrect, as the express language of § 1498 reflects—"used or ***manufactured*** by or ***for*** the United States"— draws a distinction between "used" and "manufactured," indicating that these two words should not be read to mean the same thing. *Walton v. United States*, 551 F.3d 1367, 1370 (Fed. Cir. 2009). This

Court should reject Plaintiffs' attempt to limit § 1498 to "used … by" USG, when it plainly also covers goods, like the C-100 doses, "manufactured … for" USG.

Moreover, nothing in the statute states that "use[] or manufacture[] by or for" USG requires physical possession (i.e., literally in the hands of USG personnel rather than owned by or controlled by USG) or direct physical consumption of a good by USG personnel (e.g., a dose has to be administered to military members). Plaintiffs ignore the clear evidence that USG not only accepted 100% of the doses that were "manufactured … for" USG under the C-100 Contract, but that those same purchased vaccines doses were "used" by USG to accomplish USG's goal (as stated in the C-100 Contract) of a "whole of nation effort to … ensure [vaccine] medical countermeasures are available in the quantities required to reduce SARS-CoV-2 transmission … and improve patient care, thereby mitigating the impact of COVID-19 on the nation and its people." SOF¶21. USG controlled and directed their initial ***distribution***, entered into agreements with jurisdictions governing the "***utiliz[ation]***" of the doses, and tracked "administration" of the doses as part of the efforts to accomplish USG's stated goals. SOF¶¶73–74. That some of the purchased doses were stored, at USG's request, in Moderna or USG distributor warehouses after manufacture is also irrelevant because it was done at ***USG's direction***. SOF¶¶9–11, 27–30, 73–74.

Plaintiffs want the Court to impose a fact-heavy "benefit" test that has no basis in the statute, and certainly not where USG has directly contracted for and purchased goods. The "for the benefit" test is merely a judicial gloss on how to determine if an action is "for" USG where—unlike here—there is no contract procuring the allegedly infringing article. *See Advanced Software*, 583 F.3d at 1378 ("§ 1498(a) does not require that the government be party to any contract, but may apply to activities by 'any person, firm, or corporation' for the benefit of the government."). The "for the benefit" test, which is often invoked when the authorization and

consent is unclear, ***expands*** the universe of conduct for which USG is liable under § 1498; it does not ***shrink*** the type of conduct that is "for" USG or add a third atextual requirement on top of the two express statutory requirements. In any event, USG's use of a contract with a FAR clause makes absolutely clear that the vaccine doses manufactured "for" USG also were for the "direct benefit" of USG under the government-contracting framework Congress established. 31 U.S.C. § 6303(1).

Ultimately, Plaintiffs have not identified ***a single case*** declining to apply § 1498 where USG directly contracted for the manufacture and purchase of goods and where the contract included USG's express authorization and consent "to all use and manufacture of any invention described in and covered by a United States patent in the performance of this contract." FAR 52.227-1, At. I. Plaintiffs' cited cases all arose in different contexts and are inapposite. *See* Resp. 8–9. Plaintiffs misread *Carrier*, where the Court of Claims agreed with USG that the patented equipment was not used "for" USG because USG "expressly ***withheld*** its authorization and consent." 534 F.2d at 247; *see also id.* at 249 ("[T]he Government can limit its authorization and consent as it did in this instance."). Moreover, the word "benefit" does not appear in the decision and formed no part of the court's rationale. As Moderna explained in opening, *Larson*, a Medicare reimbursement case, is factually distinguishable because USG expressly ***disputed*** that it had provided authorization and consent and the at-issue medical splints were ***not*** procured by USG. *Larson*, 26 Cl. Ct. at 371. Plaintiffs did not dispute Moderna's description of *Larson*. Op. 14–15. *Sheridan*, *Windsurfing*, and *Riles* are likewise inapposite because they did not involve USG-procurement contracts or express authorization and consent. Instead, the patentees argued that USG ***impliedly*** authorized and consented by encouraging trade engaged in by infringers (*Sheridan*, 120 Fed. Cl. at 131), granting permission to hold the Olympics in the U.S. (*Windsurfing*, 534 F. Supp. at 588), and entering into a lease with an oil company (*Riles*, 999 F. Supp. at 940–41).

Finally, Plaintiffs and their amici make a pure policy appeal by arguing that "Moderna's interpretation" of § 1498 would have "severe consequences," "impermissibly deprive patent holders of their valuable rights," and "could precipitate a major upheaval in the entrepreneurial ecosystem of our country." Resp. 9–10; D.I. 555 at 5; D.I. 550-2 at 1. But such arguments miss the mark. ***First***, Section 1498 is a liability shifting statute. *See, e.g.*, *Madey*, 307 F.3d at 1359. It does not leave a patentholder without a remedy for actual infringement, but instead provides that the patentholder's remedy must be obtained from USG in the Court of Federal Claims. 28 U.S.C. § 1498 (providing for "the recovery of his reasonable and entire compensation"). ***Second***, applying § 1498 to sales under the C-100 Contract does not "break" patents or "take" rights (Resp. 10): "The patentee takes his patent from the United States ***subject to*** the government's eminent domain rights to obtain what it needs from manufacturers and to use the same." *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 842 F.2d 1275, 1283 (Fed. Cir. 1988). Indeed, § 1498 has existed in its current form for over 75 years without leading to the abuses of power Plaintiffs and their amici raise. ***Third***, application of § 1498 here does not mean that § 1498 must apply broadly with respect to any private entity that receives any federal funding, like grant recipients, as Plaintiffs and their amici suggest. *See, e.g.*, Resp. 10. This alarmist rhetoric ignores that application of § 1498 in this specific factual context is limited—here, facing the pandemic's significant challenges to the health and operation of the nation, USG ***expressly*** assumed liability for its contractor Moderna to manufacture vaccine doses under the C-100 Contract. That contract was limited in time and scope, and USG did not provide its authorization and consent in later contracts with Moderna. PSOF¶¶75–77. Purported concerns about USG authorizing patent infringement under hypothetical broader circumstances are misplaced and better addressed through legislation.

2. Section 1498(a) Covers Infringement Claims—Direct and Indirect

Plaintiffs are wrong that § 1498 cannot apply here because § 1498's "waiver of sovereign

immunity is limited to direct infringement." Resp. 12.

First, § 1498 relieves the contractor of liability for infringement claims arising from the fulfillment of its contractual obligations; the contractor cannot be held liable for inducing or contributing. *See Zoltek*, 672 F.3d at 1324 ("plain language of the statute is clear…[T]he legislative purpose…is clear. The Supreme Court has stated that ***§ 1498(a) was meant to 'relieve the contractor entirely from liability of every kind*** for the infringement of patents in manufacturing anything for the government'"). In citing a 1980 Court of Claims decision, Plaintiffs ignore that the Federal Circuit has subsequently held that § 1498 is ***not*** limited to direct infringement. *Id.* at 1314–15, 1319 (holding that "limitation of § 1498(a) to infringement under § 271(a) is inconsistent with the plain language of the statute" and "Section 1498 makes no reference to direct infringement as it is defined in § 271(a)"); *Astornet Techs.*, 802 F.3d at 1277–78 (holding that "clear meaning of the text" barred suing contractor for indirect infringement).

Second, § 1498 bars indirect infringement claims against USG contractors "when such contractor is also liable for direct infringement and the United States government has assumed liability for such contractor's direct infringement pursuant to § 1498(a)." *Morpho Detection*, 2013 WL 5701522, at *4 (emphasis omitted). That is exactly the case here. Plaintiffs' C-100-based infringement claims—direct and indirect—stem from the manufacture, sale, and use contemplated in the C-100 Contract. Ex. 1 at 19 (describing the critical need to ensure "vaccine doses…are immediately available… for widespread ***use***"). Indeed, Plaintiffs' indirect infringement contentions are premised ***entirely*** on Moderna (allegedly) "knowingly ***selling*** or ***offering to sell*** a product especially adapted for infringing use," which falls squarely within the C-100 Contract and thus USG's authorization and consent. PSOF¶78. Section 1498(a) is directed to goods "manufactured … for" USG, which undoubtedly involves a sale. The statute would be rendered

meaningless—with contractors facing the same lawsuits the statute was designed to redirect—if a patentee could simply sidestep § 1498 by bringing indirect infringement claims.

Third, the language of the C-100 FAR clauses also confirms that USG accepted liability for ***all*** infringement, not just direct, consistent with the text and purpose of § 1498 to relieve the contractor entirely from liability. *Richmond Screw*, 275 U.S. at 343; FAR 52.227-1, Alt. I (USG "authorizes and consents to ***all use*** and manufacture of any invention …in the performance of this contract"); FAR 52.227-1 (similar); *see also* D.I. 57 at 2.

3. Plaintiffs Cannot Assert Their Baseless Fraud Theory

Plaintiffs end their opposition by absurdly asserting that the C-100 Contract was procured by fraud, and thus, § 1498 cannot apply. Resp. 13. That is an inaccurate and meritless contention.

First, Plaintiffs did not plead fraud in response to Moderna's § 1498 assertion (unlike *SmartSignal*), satisfy Fed. R. Civ. P. 9(b), or disclose "fraud" in discovery. SOF¶¶146–60.

Second**,** Plaintiffs' fabricated fraud theory does not even raise a genuine issue of material fact. Not only did Plaintiffs fail to properly raise the (baseless) fraud allegations, during this litigation, Plaintiffs instead contended that "Moderna ***did not negotiate for the inclusion of FAR Clause 52.227-1 or Alt-1 in the -0100 Contract***." SOF¶15; Ex. 119 at 17. That assertion alone defeats this theory. There is no "causal link" between the inclusion of the FAR clauses in the C-100 Contract and any alleged fraud. *Godley v. United States*, 5 F.3d 1473, 1476 (Fed. Cir. 1993) ("record must show some ***causal link*** between the illegality and the contract provisions").

Even on its own terms, Plaintiffs' fraud theory is baseless: it is premised on a single email between Moderna and USG about the '069 Patent, which ***Plaintiffs dropped*** from this case after their own infringement testing showed ***0%*** of doses of the initial version of Moderna's vaccine infringed. PSOF¶146. Moderna thus ***correctly*** told USG in 2020 that its "formula … is not covered by the Arbutus ['069] patent." P. Ex. 74; SOF¶147. Plaintiffs also omit critical USG testimony

confirming that USG was ***not*** concerned with any "specific patent" before entering into the C-100 Contract. Ex. 90 at 156:13–22. Instead, consistent with the purpose of § 1498, USG's focus was "legally procur[ing] product" to fight the pandemic, and to do so, it "needed a contract in place." *Id*. If USG had wanted to avoid liability for any potential patent infringement, USG had the option to include an indemnity clause. 48 C.F.R. § 27.201-1(d) (USG "may require a contractor to reimburse it for … patent infringement … by inserting [FAR] 52.227-3, Patent Indemnity.").

Third, even after this lawsuit was filed, USG affirmed its authorization and consent in its Statement of Interest. D.I. 49 at 17 ("to the extent that any doubt otherwise existed, the Government's filing of ***this statement of interest*** and confirmation of its authorization and consent should resolve the issue"); D.I. 57. Plaintiffs also took extensive fact discovery, lasting several years, relating to the C-100 Contract, yet tellingly, they cite no documents or testimony where any individuals from USG discussed or asserted any fraud allegations like what Plaintiffs now allege.

Fourth, a district court lacks authority to declare a contract void in a patent-infringement action, especially not at the request of outsiders to the contract like Plaintiffs. Plaintiffs' dissatisfaction with the application of § 1498 does not confer standing to invalidate the underlying contract. *Cf. In re Vic Supply Co, Inc.*, 227 F.3d 928, 931 (7th Cir. 2000) ("Obviously the fact that a third party would be better off if a contract were unenforceable does not give him standing to sue to void the contract."). The only case Plaintiffs cite to suggest they may challenge the validity of the C-100 is an unpublished district court decision involving an allegedly fraudulently induced contract that was not fully performed. *SmartSignal*, 2006 WL 1343645, at *1. By contrast, Plaintiffs seek to interfere in, and void, a contract that has been fully performed by both parties, where neither party contested validity or enforceability. Plaintiffs cite ***no*** case where a court has voided a contract to prevent application of § 1498, and it would be profoundly at odds with

§ 1498's purpose to let a stranger to the contract—including, most pointedly, the patentee seeking to do exactly what § 1498 forbids—void the contract to set aside § 1498's protection.

B. Prosecution History Estoppel (PHE) Bars Plaintiffs' DOE Theories

1. Amendment-Based Estoppel Bars Plaintiffs' DOE Theories

Plaintiffs agree they narrowed the claims by removing "about," thereby disclaiming +/- 10, 20, 30 mol%. Resp. 19. But Plaintiffs seek to avoid the consequences of that narrowing by mischaracterizing the *Markman* opinion and ignoring *Festo*, which presumes Plaintiffs disclaimed "***all*** territory" between the original and narrowed claim, not just ***part*** of it. 344 F.3d at 1367. Plaintiffs also assert the tangential exception by misreading the file history and MacLachlan. But "an amendment made to avoid prior art that contains the equivalent…is ***not tangential***." *Id.* at 1369. There are no genuine disputes of material fact, and summary judgment should be granted.

a. Plaintiffs Mischaracterize the Court's *Markman* Opinion

The Court's *Markman* order could not have been clearer: "When Plaintiff removed the phrase 'comprising about,' it … clearly disclaimed these broader ranges [+/- 10, 20, 30 mol %] and not the scientific conventions of rounding …" D.I. 266 at 21–22. Plaintiffs nonetheless assert that Moderna's PHE arguments were rejected during *Markman*. Resp. § II.B.1.a. They were not. Indeed, Plaintiffs admit that the issue decided at *Markman* (literal scope with rounding) is different from the issue now before the Court (equivalent scope with compositions outside the literal range). SOF¶¶ 83, 84; D.I. 266 at 21–22. Indeed, Moderna's PHE argument focuses on the ***gap*** between the literal claim scope and what Plaintiffs argue infringes under DOE. *Id.* at 24–26.

b. *Festo* Controls Scope of Disclaimer—Not Attorney Argument

Plaintiffs argue that they "only disclaimed the broader ranges disclosed ***in the prior art (MacLachlan)***, and not narrower accused amounts not disclosed in the prior art." Resp. 19; SOF¶ 110. But the territory Plaintiffs are presumed to have disclaimed is ***not*** limited to what was

"in the prior art" as Plaintiffs suggest. Rather, the Supreme Court's decision in *Festo* "imposes the presumption that the patentee has surrendered ***all*** territory between the original claim limitation and the amended claim limitation," not ***part*** of it as Plaintiffs suggest. *Festo*, 344 F.3d at 1367.

Here, Plaintiffs do not dispute stating that "to determine the scope of the narrower claims…you ***get rid of*** that [+/-]10, 20, 30 [mol%]," that was recited in the original claims. SOF¶¶ 101–104, 107. Plaintiffs recognized this at *Markman* with a slide comparing the original and amended claim, plainly showing the territory disclaimed under *Festo*. Op. 22–23; SOF¶ 84. Notably, Plaintiffs' slide, which they now ignore, does not show that 45–50 mol% remained in the amended claim as they now suggest. Ex. 43. Such "[p]ost-hoc, litigation-inspired argument cannot be used to reclaim subject matter that the public record in the PTO clearly shows has been abandoned." *Desper Prods., Inc. v. QSound Labs, Inc.*, 157 F.3d 1325, 1340 (Fed. Cir. 1998).

c. Parties Agree on When Tangential Exception Does Not Apply

Plaintiffs ***agree*** that if they had "amended to avoid prior art that 'disclosed' or 'taught the use' of the alleged equivalents, the tangentiality exception would not apply." Resp. 21. Moderna agrees, and—as explained in § II.B.1.d—that is ***exactly*** what happened here. Plaintiffs mischaracterize Moderna's argument as relying on a "bright-line rule" that the tangential exception does not apply where an amendment and equivalent relate to the same claim element. Resp. 20. That is false: Moderna argues that tangentiality does not apply because the alleged equivalent was "***both*** within the surrendered territory and the ***prior art MacLachlan***." Op. 25.

d. Plaintiffs Rewrite the File History to Argue Tangentiality

In arguing that the tangential exception applies, Plaintiffs misread the file history to suggest that the prior art did not disclose the alleged equivalents. Resp. 20–22.

First, Plaintiffs myopically focus on an anticipation rejection and ignore that the original claims were ***also*** rejected for obviousness based on overlapping ranges in MacLachlan that

disclose the alleged equivalents. Specifically, Plaintiffs claim that the sole reason for the narrowing was "to address a specific legal doctrine that applies when 'overlapping ranges' are present in the prior art." Resp. 20 (citing *Atofina*, *UCB*). But *Atofina's* "specificity" doctrine applies only to anticipation, not obviousness. *Atofina,* 441 F.3d at 998–1000. In *UCB*, relied on by Plaintiffs, prior-art Muller taught a 1.5–5% PVP range that overlapped with the claimed range of 4–6% PVP. *UCB*, 65 F.4th at 686. The Federal Circuit held it was error not to require *Atofina's* "specificity" to that prior-art range for anticipation, but affirmed a finding that the ***same range*** rendered the claims obvious. *Id*. at 688–690. Here, in rejecting the claims for obviousness, the Examiner found that "***MacLachlan also teaches*** … cationic lipid is from about 2 mol % to about 60 mol %." Ex. 73 at 4; SOF ¶ 61; Ex. 75 at 8; SOF ¶ 76. Plaintiffs do not dispute that (1) the narrowing was made to overcome the obviousness rejection (SOF ¶ 76, 103–04, 107), and (2) the cationic range taught in MacLachlan (2–60 mol %) includes the alleged equivalent (45-50 mol %), which confirms the tangential exception cannot apply. SOF ¶110; Resp. 20 (admitting "MacLachlan does" disclose 2–60 mol%); *Festo*, 344 F.3d at 1369 ("[A]n amendment made to avoid prior art that contains the equivalent in question is ***not tangential***; it is ***central*** to allowance of the claim."). The same is true for the other claimed lipid ranges Plaintiffs seek to expand with DOE. SOF¶¶ 108–14. This history of the obviousness rejections ***alone*** forecloses tangentiality.

Second, Plaintiffs argue that the tangential exception applies because the narrowed claims still overlap with the prior art. Resp. 21. But they do not dispute that the Examiner withdrew all rejections (§§ 102, 103, ODP) ***because of*** the narrowing—which ***reduced***, though not completely avoided, that overlap—along with arguments of unexpected results directed at 50–65 mol% cationic lipid in the amended claims. SOF¶¶ 72–78; Ex. 72 at 9 ("***increased*** amounts of cationic lipid, e.g., … ***50 mol % to 65 mol %*** … provide ***unexpectedly superior advantages***"); D.I. 266 at

20; *Biagro W. Sales, Inc.*, 423 F.3d at 1306.423 F.3d 1306 (no tangentiality where "reason for the amendment" and the "accused equivalent" "both relate[d] to the concentration").

Third, even the anticipation rejection forecloses tangentiality. *Atofina* requires the overlapping prior-art range to describe "the ***claimed*** range with sufficient specificity." 65 F.4th at 687 (cleaned up). This necessarily compares the overlap between the ***claimed range*** and prior art. And while applicants' narrowed claims may have passed muster (50–65 mol % vs. 2–60 mol% in MacLachlan), the Examiner did ***not*** allow the claimed ranges to be as broad as originally proposed. Resp. 21; SOF¶ 72–75; Ex. 73 (citing Ex. 57). Plaintiffs now seek to rebroaden that range by 5 mol%. SOF¶ 106. If Plaintiffs suggest that they ***could have*** obtained claimed as low as 45 mol% cationic lipid despite MacLachlan, and gave up more than they needed to, that argument is contrary to law. *Pharma Tech Sols., Inc. v. LifeScan, Inc.*, 942 F.3d 1372, 1382 (Fed. Cir. 2019) (If patentee "ceded more claim scope than necessary to overcome []prior art[, that] does not mean that the tangential" exception applies); *Amgen,* 931 F.3d at 1161 ("Clear assertions…whether or not actually required to secure allowance of the claim, may also create an estoppel.")(cleaned up).

Fourth, Plaintiffs' cited cases are inapposite, because in each, the prior art did not disclose the alleged equivalent. *Eli Lilly* narrowed claims from a genus of compounds to a specific salt form of a compound ("pemetrexed disodium"), and accused an equivalent salt form of that ***same compound*** ("pemetrexed ditromethamine"), whereas the prior art taught a ***different compound*** ("methotrexate"). 933 F.3d at 1325–27, 1331–32. In *Bio-Rad*, the patentee narrowed to "make clear that the carrier fluid and the microchannel wall ***should be chemically distinct***," whereas the alleged equivalent ("microchannel walls containing a nominal amount of fluorine") was ***not chemically distinct***. 967 F.3d at 1365; *Primos*, 451 F.3d at 849 (accused equivalent outside disclaimed territory). And in *Regents of Univ. of Cal.*, the prior art did not even mention the

equivalent. 517 F.3d at 1378. Unlike Plaintiffs' cases, here, the ***same composition*** (cationic lipid) is in the original claims, amended claims, the prior art, and the alleged equivalent; and the alleged equivalent ***amount*** (45-50 mol%) ***is*** disclosed in MacLachlan (2-60 mol%). SOF¶ 110.

Finally, Plaintiffs spill much ink on Moderna's design-around. Resp. 17–18. But Plaintiffs' assertions are not only untrue; they are ***irrelevant*** to PHE. *Pioneer Magnetics, Inc. v. Micro Linear Corp.*, 330 F.3d 1352, 1356 (Fed. Cir. 2003) ("Only the public record of the patent prosecution, the prosecution history, can be a basis for [determining the reason for amending].").

2. Argument-Based PHE Bars Alleged Cationic Lipid Equivalents

Plaintiffs again begin by wrongly asserting that the Court rejected Moderna's argument-based PHE defense. Resp. 25. Not so. The portion of the *Markman* opinion Plaintiffs refer to (D.I. 266 at 28–31) relates to the '378 patent, and Moderna's amendment-based PHE argument is limited to the '359 and '435 Patents. The Court's analysis of the '378 claims and file history during *Markman* therefore has no bearing on argument-based PHE.

Plaintiffs argue that they did not "unmistakably restrict[] an 'increased' or 'higher' concentration of cationic lipid specifically to 50 mol % or more." Resp. 25. Not so. Plaintiffs explicitly based unexpected results on "***increased*** amounts of cationic lipid, ***e.g.,*** one or more ***cationic lipids comprising from 50 mol %*** to 65 mol %." Ex. 75 at 9; SOF¶¶ 63–65, 69, 77–78, 166; Exs. 64–67. Likewise, Plaintiffs' argument that they only "distinguished the invention from prior art disclosures of 40 mol % cationic lipid or less," Resp. 25–26, ignores that they distinguished from the ***ranges*** taught by MacLachlan (2-60 mol%), not just specific ***formulations***. SOF¶¶ 60–79. Here, Plaintiffs' alleged equivalent is ***the same lipid***, in amounts (45-50 mol%) far closer to the prior art (40, 2-60 mol%) than their alleged invention (57 mol%). Thus, *Conoco* (Resp. 26) does not apply, as there, the court found disclaiming a specific prior art chemical species did not disclaim ***other*** chemically equivalent species. 460 F.3d 1349, 1364 (Fed. Cir. 2006).

C. Plaintiffs' Motion for SJ of Definiteness of the Ratio Patents Should Be Denied

Plaintiffs' motion for summary judgment of definiteness for the Ratio Patents should be denied because it ignores evidence of outcome-determinative differences between methods of measurement and relies on mischaracterizations of Dr. Prud'homme's opinions.

1. Plaintiffs Fail to Show the Ratio Patents Provide a Method of Determining the Metes and Bounds of the Claims.

"[W]here different approaches to measurement are involved" "the patent and prosecution history must disclose a single known approach or establish that, where multiple known approaches exist, a [POSA] would know which approach to select." *Dow Chem.,* 803 F.3d at 630 (cleaned up); *Saso Golf, Inc. v. Nike, Inc.*, 843 Fed. App'x 291, 296 (Fed. Cir. 2021). Plaintiffs fail to show the asserted claims of the Ratio Patents meet this standard because the specification does not disclose ***any method*** of measurement the lipid "mol%" of a single particle as claimed, and because different methods that Plaintiffs argue ***indirectly*** measure that give rise to meaningfully different results. PSOF¶¶ 24, 84–89; *see Teva,* 789 F.3d at 1341 (finding claim indefinite where molecular weight could be measured by three methods yielding different results and intrinsic record did not guide which method to use)*; Saso*, 843 Fed. App'x at 296 (similar).

The Ratio Patents recite three or four lipid components in ranges in "mol%" "of the total lipid present in the particle." PSOF¶ 12. The specification of the Ratio Patents, however, does not describe how to determine the "mol%" of lipids in individual particles or the formulation. PSOF¶¶ 84–89. The Ratio Patents refer to the mol% of both ***input*** (i.e., the amounts of lipids going into the recipe, known as the "target") and ***output*** (i.e., as measured in the formed particles). PSOF¶¶ 90–91. The Ratio Patents contain tables of formulations in "mol%" that are not expressly labelled as input or output, though the inventors admitted they report input. PSOF¶ 91. Although the claims recite amounts of lipid in "***a*** particle," the specification does not disclose lipid amounts in ***any***

single particle, let alone a method that could measure it—because it is impossible to do so. PSOF¶¶ 22, 24. Instead, Plaintiffs suggest it is "standard" to measure lipid content of aggregates of particles (i.e., formulation). Resp. 32–33. But when the aggregate results did not suit Plaintiffs, they relied on purported 'sub-populations' of particles after they were fractionated.[3] PSOF¶¶ 24, 88–89. But since none of these methods—e.g., measuring aggregates or sub-populations—are described in the specification and each give meaningfully different results, the claims are indefinite. PSOF¶¶ 22, 24, 86, 89, 92. *See Teva,* 789 F.3d at 1341; *Saso*, 843 Fed. App'x at 296.

Plaintiffs incorrectly suggest there are only "hypothetical" differences between different methods, and that any such differences are not "outcome-determinative." Resp. 29. But Plaintiffs ignore the extensive record that a variety of tests produced meaningfully different results. PSOF¶¶ 20, 25, 31, 92. Indeed, Plaintiffs have cycled through different tests ***because*** they have materially different results. Plaintiffs first accused Moderna's target ratio (i.e., input), then aggregate lipid content, and finally its experts' custom-designed-for-this-lawsuit fractionation methods measuring purported sub-populations of particles. PSOF¶¶ 24, 82–83, 88–89, 92. For example, Plaintiffs' expert tested both aggregate (non-fractionated) and fractionated samples and obtained materially different results, i.e., the same batch resulted in lipids amounts inside and outside certain claimed ranges. PSOF¶¶ 82. Plaintiffs' expert even generated materially different results from one custom-designed fractionation method to another (the same purported technique). PSOF¶¶ 24, 83, 88–89, 92. These differences are nothing like the "theoretical minor differences" between methods in *Takeda*, 743 F.3d at 1367, instead demonstrate that "application of the different methods result in materially different outcomes for the claim's scope," *Saso*, 843 Fed. App'x. at 296. That evidence

[3] Plaintiffs' fractionation methods involve spinning samples millions of times by ultracentrifuge, and then splitting the resulting sample into 'fractions.' Both the pre-fractionation sample and the resulting 'fractions' have millions of LNPs. PSOF¶¶ 22, 24.

at the very least raises disputed issues of material fact warranting denial of Plaintiffs' motion.

With regard to [redacted] that Plaintiffs (frivolously) accuse of infringement, in addition to the general lack of guidance to measure "mol%" described above, there are further factual disputes about whether POSAs could measure lipids of those [redacted] preventing a finding of definiteness. Resp. 30. As an initial matter, Dr. Prud'homme ***does*** address [redacted] that Plaintiffs actually accuse. *Id.*; PSOF¶¶ 30–35. Those [redacted] Plaintiffs' seeming confusion stems from ignoring the extensive evidence Dr. Prud'homme analyzed showing that those [redacted]. PSOF¶¶ 30, 31, 34–35. Dr. Prud'homme also opined that the Ratio Patents provide no guidance for measuring [redacted] PSOF¶ 35. In response, Dr. Murthy fails to show a method of measuring such particles, which cannot establish definiteness for that separate and independent reason. PSOF¶ 87. *See Kaneka Corp. v. Zhejiang Med. Co., Ltd.*, 2018 WL 2718036, at *13 (C.D. Cal. Apr. 5, 2018), *aff'd sub nom. Kaneka Corp. v. Xiamen Kingdomway Group Co.*, 767 Fed. Appx. 998 (Fed. Cir. 2019) (finding for "mole percent" term, it "is for the trier of fact to determine what sample collection and handling methods [POSAs] understood to be appropriate").

2. Dr. Prud'homme's Opinions Applied Proper Legal Standards

Dr. Prud'homme accurately set forth the indefiniteness standard, applied it to the claims, and concluded that they were indefinite. PSOF¶¶ 81. Plaintiffs reduce his lengthy opinions to a snippet to argue that he improperly considered whether it was possible to determine infringement. Resp. 27-28. Instead, he understood "that claims can be found indefinite if a POSA cannot determine whether a given composition falls inside or outside of the claims, despite understanding the meaning of specific words in the claims." Ex 84 ¶ 150. That is precisely the analysis the law

requires—determining the scope of the claims with reasonable certainty. *See Nautilus*, 572 U.S. at 901. Indeed, Dr. Prud'homme did not even mention ***infringement*** or the ***accused product*** in his opinions on indefiniteness. Ex 83 ¶¶ 227–233. Thus, his opinions do not conflict with Plaintiffs' cited cases like *SmithKline,* 403 F.3d at 1340–41. Resp. 26, 28. Regardless, the "test for definiteness 'does not require that a potential infringer be able to determine ex ante if a particular act infringes the claims'"; instead, the patentee must "apprise the public of what is still open to them" such that "[POSAs] could determine ***whether or not an accused product or method infringes the claim***." *Niazi Licensing Corp. v. St. Jude Med. S.C., Inc*., 30 F.4th 1339, 1346-47 (Fed. Cir. 2022) (cleaned up). This does not conflict with cases holding that "disputes over infringement do not make a patent claim indefinite," *Ironburg Inventions,* 64 F.4th at 1290, because while infringement allegations do not control the scope of the claim, understanding that scope is necessary to understanding infringement.

D. Summary Judgment of Indefiniteness of the '651 Patent Should Be Granted

The extensive evidence and undisputed facts showing POSAs could not define, let alone measure "fully, as distinct from partially" encapsulated mRNA confirms Moderna's motion for summary judgment should be granted, and Plaintiffs' motion for definiteness should be denied.

1. "Fully, as distinct from partially," is anything but clear.

Plaintiffs contend that because the Court construed the claim term "fully encapsulated" mRNA, "that resolve[d] any possibly ambiguity about the *scope* of the claims." Resp. 31. But "amenable to construction" is not the standard for definiteness. *Nautilus*, 572 U.S. at 901.

To prop up their flawed argument, Plaintiffs assert that Moderna's expert opinions were "conclusory." Resp. 31. That is belied by the 30 pages of analysis that Dr. Prud'homme provided. Ex 61 ¶¶ 127–39; Ex 84 ¶¶ 32–64. Likewise, Plaintiffs' argument that Moderna's "experts also did not identify uncertainty about the scope of the term" (Resp. 31) is incomprehensible—that is

exactly what Dr. Prud'homme opined on in his report. *See* Ex 61 ¶¶ 127–39; Ex 84 ¶¶ 32–64. Thus, far from "bereft of factual support" (Resp. 31), Dr. Prud'homme's 30 pages of analysis are evidence of the many problems with the term "fully encapsulated." *See also* Op. 28–35.

As to "fully," Plaintiffs repeat the same failed arguments they advanced during Markman, relying on Dr. Murthy to argue that it means "fully contained inside." Resp. 33; D.I. 266 at 32–37; *see also* Resp. 31 (noting Dr. Prud'homme's agreement with the Court that "a POSITA would only count those strands that are fully contained in the vesicle"). But the Court construed the term to mean "fully, as distinct from partially" encapsulated, and Plaintiffs have failed to explain how a POSA would differentiate between the two states—if a POSA cannot define or measure either state, there is no way for a POSA to determine with "reasonable certainty" the scope of "fully encapsulated." Op. 28–35. As to "partially," although the Court found that "part-in-part-out" mRNA is one type of partial encapsulation, the Court did not construe "partially encapsulated" itself, let alone define all possible examples of it. D.I. 266 at 32–33. Indeed, Plaintiffs admit that at least two ***additional*** types of "partially encapsulated" mRNA exist. SOF¶¶ 121 (disordered mixtures), 122 (surface-adhered). The Court therefore did not "resolve[] any possible ambiguity" as Plaintiffs suggest. *See* Resp. 33. There is no guidance in the specification as to what "partially encapsulated" means or how to measure it, and Plaintiffs have not pointed to any consistent meaning or method of measurement known to POSAs by 2002. Thus, unlike *SmithKline*, where the "claim recite[d] in clear terms a discernible chemical structure," here Plaintiffs cannot meaningfully explain the scope of the claims. 403 F.3d at 1341. And unlike *SmithKline*, Moderna's defense is not premised on an inability to measure "fully, as distinct from partially" encapsulated mRNA ***in the accused product***; it is premised on the inability to measure it in ***any*** "lipid vesicle."

2. Plaintiffs' "standard" test cannot quantify "fully" encapsulated mRNA

Plaintiffs' arguments and recited case law that "a claim is not indefinite if a [POSA] would

know how to utilize a standard measurement method" is a strawman—there is no standard measurement method here. Resp. 32–33. This Court already found that "partially encapsulated" mRNA includes the state where the mRNA is part-in-part-out of the "lipid vesicle." D.I. 266 at 36–37. The Court also found that the alleged "standard" dye-exclusion method ***cannot*** quantify "fully, as distinct from partially" encapsulated nucleic acid because it would include both fully encapsulated and part-in-part-out mRNA. D.I. 266 at 37. Plaintiffs claim the part-in-part-out mRNA "need not be measured" because it does not exist (Resp. 35), but Plaintiffs ignore undisputed evidence, including testimony from Plaintiffs' scientists and experts, confirming that it does indeed exist. SOF¶¶122–23, 135. Plaintiffs also claim that "partially encapsulated" mRNA cannot exist ***in LNPs***, but the claims recite "lipid ***vesicle[s]***," and "lipid-nucleic acid particle[s]," not "LNPs." SOF¶117. Moreover, Plaintiffs' claim of "impossibility" is belied by their expert Dr. Mitchell filing a patent claiming ***LNPs*** with "at least partially encapsulated" mRNA. PSOF¶ 80. While Plaintiffs claim Moderna is "nonsensical" for suggesting partial encapsulation exists, that is how the ***inventors***, and not Moderna, defined the claims.

3. The "commonly used" methods led to meaningfully different results.

Plaintiffs have not refuted that Blenke showed seven "commonly used quantification methods for nucleic acids" differed by up to 39% for the ***same*** samples. SOF¶¶140–42. That is a far cry from *Takeda* (Resp. 32), where there was a "high degree of correlation" between methods, and "***no*** evidence" they "in fact produced significantly different results for the same sample." *Takeda,* 743 F.3d at 1367. Plaintiffs' reliance on *Presidio* (Resp. 35) is also misplaced; those claims did not require the measured property to be "at any particular level." *Presidio,* 875 F.3d at 1377. Here, the inability to measure the claimed properties, and the material differences in the various methods of measuring the claimed properties, is demonstrative of indefiniteness. In *HZNP Medicines v. Actavis*, even though the specification provided different measuring tests (which the

'651 does not), because "those tests d[id] not provide consistent results upon which a POSITA would be able to evaluate [the claim]," the claim was indefinite. 940 F.3d 680, 698 (Fed. Cir. 2019). Plaintiffs also try to recast Blenke's methods as "non-standard" and "aberrant," but Blenke identified them as "commonly used." SOF¶¶ 139–40. And Dr. Murthy conceded those methods were available in 2002. SOF¶¶ 138, 143. Blenke's authors did ***not*** generate differing results by using a "defective device," as occurred in *Janssen,* 97 F.4th at 937. That Blenke did not test mRNA (just like '651 patent) does not undermine its conclusions comparing methods of quantifying "nucleic acids" generally. SOF¶¶ 139–42, 144. And though Blenke notes one method may be more suited to mRNA, Plaintiffs cannot rebut that the other six generally applicable methods showed 39% variability, which is undoubtedly outcome-determinative. SOF¶¶ 139–42.

4. Plaintiffs' Remaining Arguments Do Not Create Fact Questions

Plaintiffs conclude with a hodgepodge of alleged factual disputes that are squarely foreclosed: First, Moderna explained why knowing how to measure "partially encapsulated" mRNA ***is*** required to understand the scope of the claims. Op. 32–33; *see* § II.D.2. Second, Dr. Murthy's allegations that one can differentiate between "fully" and "partially encapsulated" using dye-exclusion is belied by the record and the *Markman* opinion. D.I. 266 at 37; § II.D.2; SOF¶¶ 122–32. Third, Moderna does not "ignore" evidence that there will likely be no "partially encapsulated" mRNA, which Plaintiffs admit exists. *See* § II.D.2. Fourth, whatever Dr. Murthy's contrived opinions are about understanding the scope of the claims, it is undisputed that the specification provides no guidance and there is no commonly understood meaning as to the term "fully, as distinct from partially" encapsulated. Op. 29–32. Finally, Plaintiffs are correct the Blenke does not create a triable issue of fact—instead, it confirms that there was undisputedly no consistent method of measuring encapsulation at the alleged priority date. *See* § II.D.3.

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September 5, 2025

CERTIFICATE OF SERVICE

I hereby certify that on September 5, 2025, I caused the foregoing to be electronically filed with the Clerk of the Court using CM/ECF, which will send notification of such filing to all registered participants.

I further certify that I caused copies of the foregoing document to be served on September 5, 2025, upon the following in the manner indicated:

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